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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,376	07/09/2007	David G. Burton	8627-1391 (PA-5511-PCT/US)	8852
48003 7590 06/30/2010 BRINKS HOFER GILSON & LIONE/CHICAGO/COOK PO BOX 10395 CHICAGO, IL 60610			EXAMINER WEBB, SARAH K	
			ART UNIT 3731	PAPER NUMBER
			MAIL DATE 06/30/2010	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/593,376	<b>Applicant(s)</b> BURTON ET AL.	
	<b>Examiner</b> SARAH WEBB	<b>Art Unit</b> 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,12-16,22,24 and 25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,12-16,22,24 and 25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/7/2010 has been entered.

### ***Response to Arguments***

2. Applicant's arguments filed 6/7/2010 have been fully considered but they are not persuasive. Applicant's arguments fail to specifically point out structural differences between the claimed invention and the cited art. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant argues that Lee does not disclose the claimed transitions, because his transitions have a thinner wall thickness than the working length and Lee does not mention the transitions. Lee discloses the general geometry of a balloon with a central working length, proximal and distal tapers, and transitions that have large radii, so it is irrelevant whether the walls are thinner in some areas.

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Applicant argues that Bleam solves the problem in a different way by changing the angle and length of the tapered portions and does not mention the transition radii. Bleam simply uses different language to describe the process of smoothing the transition between the working length and tapers. Decreasing the angle of the tapers alters the angle at which the tapered regions meet the working length so that the transition is smoother and less abrupt. This smooth angle of intersection would result in a curved transition with a greater radius. Lengthening the tapered portion also has the same effect. Therefore, Bleam's teachings of smoothing the transitions of balloon tapers are relevant to the claimed invention.

Applicant argues that the figures of Lee and Bleam do not suggest the claimed invention, because the transitions only *look* smooth when the balloon is inflated and have significant differences in a deflated state. Since the deflated state is not illustrated, it is uncertain whether this assumption is true. Examiner notes that the Figures of Lee and Bleam look substantially similar to the drawings of the instant application. Lee states that the tapers are substantially flattened in the deflated state (paragraph 23), so the radii would be significantly large. Lee goes on to teach that in the flattened state, the balloon has less resistance as it is guided through vasculature. Additionally, the dimensions provided in Applicant's specification appear to correspond to inflated balloons, as explained in the 112 Rejections section below.

***Response to Amendment***

3. The declaration under 37 CFR 1.132 filed 6/7/2010 is insufficient to overcome the rejection of claims 1, 3, 4, 12-16, 22, 24, and 25 based upon the combination of Bleam and Lee, as set forth in the last Office action because: Applicant's arguments fail to specifically point out structural differences between the claimed invention and the cited art as discussed above.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 3, 4, 12-16, 22, 24, and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims list various radii of the transition portions that correspond to different balloon diameters. These dimensions appear in the specification in Table 2 on page 14. While the independent claims require that these dimensions be met *before inflation* of the balloon, the specification does not state that these dimensions correspond to balloons in the deflated state. Rather, it appears that the different diameters listed correspond to the sizes of different *inflated* balloons.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1, 3, 4, 12-16, 22, 24, and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims require various radii of the "working length-to-taper transition portion" that correspond to various balloon diameters. The limitations regarding the radii of the transitions are indefinite because:

- a. the claims do not specify to which portion of the balloon that the diameters correspond
- b. It is unclear whether the balloon diameters correspond to a deflated state or an expanded state. The claim states "radius *before inflation*..." but Table 2 of the specification appears to provide diameters for inflated balloons.
- c. It is unclear whether one balloon transition zone should have each of the radii at different diameters as it is inflated or whether each listed radii corresponds to separate embodiments.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 3, 4, 12-16, 22, 24, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee (United States Patent Application Publication Number 2003/0139762) in view of Bleam (United States Patent Number 5,797,878).

Lee discloses a dilation catheter comprising an elongate catheter body with a lumen and a balloon (40) in communication with the lumen, the balloon comprising a working length (44) surrounded by proximal and distal regions, each of which comprises a taper-to-neck transition and a working length-to-taper transition (proximal taper 48 includes a proximal taper-to-neck transition near ref. 42, and a proximal working length-to-taper transition at ref. 40, similar transitions are found at distal taper 50). Lee discloses that the balloon is between 1.5 and 15 mm in diameter (paragraph 2).

Lee teaches that the tapers of the balloon should be smooth in order to allow the balloon to traverse stenoses ((paragraph 5), but Lee does not disclose specific radii of the transitions between working and taper portions when the balloon is in a deflated state. Bleam discloses another balloon with a working length and proximal and distal tapers. Bleam seeks to minimize the frictional forces during movement of the deflated balloon through vasculature (column 2, lines 12-22), and teaches that smaller taper angles and longer taper lengths can reduce these frictional forces (col. 2, lines 40-67).

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Although not specifically recited, decreasing the angles in the transition zones and lengthening the tapered portions inherently increases the radius of the transitions. It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize larger radii in the transitions of the Lee balloon, as Bleam teaches that smoothing the transitions between taper and working portions of a balloon minimizes frictional forces during movement of a balloon in its collapsed state. Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize transitional radii within the ranges listed in claims 1, 3-4, 22, and 24-25 for the balloon diameters specified, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding claims 12-14, Bleam discloses the angles at the taper-to-neck and working length-to-taper transitions being equivalent (col. 6, lines 57-65), and discloses that the balloon ends 22 and 24 are symmetrical (col. 6, lines 23-31). Regarding claims 15 and 16, Lee discloses the proximal and distal tapers being asymmetric, and the diameters along the taper being either constant or varied (paragraph [0031]). As such, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide varying transitional radii amongst any of the four transition zones to accommodate the various taper diameters. Regarding claim 22, Lee further discloses inserting a dilation catheter through a conduit, inflating the balloon, deflating the balloon, and applying a force to the catheter to remove the balloon (paragraphs [0004] and [0005]).



***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SARAH WEBB whose telephone number is (571) 272-5749. The examiner can normally be reached on 9:00am - 5:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SARAH WEBB/  
Examiner, Art Unit 3731

/Anhtuan T. Nguyen/  
Supervisory Patent Examiner, Art Unit 3731  
6/28/10